



# RESEARCH PROTECTIONS UPDATE



*News and Comments on the Protection of Human Subjects in Navy and Marine Corps Research*

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## DON HRPP Spotlight

**LCDR Matthew Shipman** is a U.S. Navy Aerospace and Operational Physiologist, currently assigned to the Bureau of Medicine and Surgery as the Military Deputy Director for DON HRPP. In this role, he provides leadership and subject matter expertise on military operations, safety and risk management, human factors and biomedical research. He is very supportive of the research community's efforts to improve warfighter performance and survivability. LCDR Shipman holds a Doctorate in Biochemistry from Montana State University, Bozeman and board certification as a Certified Safety Professional from the Board of Certified Safety Professionals.



LCDR Shipman joined DON HRPP in June 2024, arriving from Commandant of the Marine Corps Safety Division where he served as the Aeromedical Safety Officer to the Commandant and oversaw all Navy personnel assigned to the United States Marine Corps (USMC) aeromedical safety and operational physiology billets. In this role, he led Department of Defense (DoD) efforts to improve classification of human factors, led the redesign of the USMC underwater egress training/survival swimming program, and led delivery of critical aeromedical and operational physiology support to USMC aviation and ground forces.

Previous duty stations include Naval Medical Research Unit Dayton (NAMRU-D), Marine Aircraft Group 31 (MAG-31), and Aviation Survival Training Center (ASTC) Jacksonville. Key accomplishments in these billets include:

- Led the design and acquisition of an expanded analytical core facility at the Environmental Health Effects Laboratory at NAMRU-D
- Successfully conducted a high-risk search and rescue exercise at sea for MAG-31
- Led his unit in delivery of high-risk aviation survival training at ASTC Jacksonville

LCDR Shipman looks forward to working with the DON HRPP team to help ensure continued risk mitigation efforts and successful conduct of human subjects research to benefit the joint warfighter.

## Authorized Operational Activities

The 2018 Common Rule (32 CFR 219) carves out four activities that are deemed not to be research, including scholarly and journalistic activities, public health surveillance activities, information collected solely for criminal justice/investigative purposes, and authorized operational activities in support of intelligence, homeland security, defense or other national security missions.

Authorized operational activities is particularly applicable within the DoD. The DoDI 3216.02 defines authorized operational activities as "activities carried out solely in support of the DoD mission... to deter war and protect the security of the United States... subject to approval by the DoD Component head or Secretary of Defense, including subordinate agencies heads who have been delegated authority to study, evaluate, improve, or otherwise assess DoD performance, quality, and capability." Defense Health Agency guidance further suggests that the authority to study, evaluate, improve, and examine may originate from a "DoD or Component issuance, such as a Directive, Instruction, or Regulation" (GD-19-010 Authorized Operational Activities).

If an activity will be conducted solely for an operational purpose under an established directive, instruction, or regulation, then it is likely not considered research. However, investigators are highly encouraged to discuss such projects with their Command HRPP for guidance and appropriate determinations. Including guidance on such activities within HRPP policies can also be helpful to provide clarity and consistency for researchers. This can help ensure that all activities conducted within the organization are consistent with ethical guidelines and regulations, and that any necessary review and approval processes are followed.

### **\*\*UPCOMING EVENTS\*\***

**The 2024 Public Responsibility in Medicine & Research (PRIM&R) Annual Conference will be held in Seattle, Washington on 17-20 November.**

**Registration is now open at:** <https://primr24.eventscribe.net/>

Join us for a no-host social the evening of 19 November.

**Please RSVP by 8 November** to receive more details:  
[usn.ncr.bumedfchva.mbx.don-hrpp@health.mil](mailto:usn.ncr.bumedfchva.mbx.don-hrpp@health.mil)

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### **Command Learn and Share Series (CLaSS)**

The first CLaSS session will be held virtually on 14 November.  
Information to attend is forthcoming.

## NEWS & INFORMATION

### New Proposed FDA Draft Guidance

Earlier this year, the Food and Drug Administration and the Office for Human Research Protections released newly proposed guidance with recommendations to assist Institutional Review Boards, investigators, and sponsors that oversee human subjects research with the development and presentation of key information to include in the informed consent documents.

This guidance aims to improve the informed consent process for human subjects research. It suggests that consent documents should be organized and presented in a way that is easy for potential subjects to understand. This includes using visual aids such as “bubbles” to organize important information and using plain language throughout the document. The goal is to help potential subjects make informed decisions about whether or not to participate in a study. A complete version of the draft guidance is available at: <https://www.fda.gov/media/176663/download>.

### Military Health System Research Symposium Highlights

The Director DON HRPP, CDR F. Jay Haran, and the DON HRPP Military Deputy Director, LCDR Matthew Shipman, attended the Military Health System Research Symposium (MHSRS) conference in Kissimmee, FL 25-29 August 2024. During the conference they met with numerous representatives from several Navy commands and were able to network, collaborate, and discuss a variety of topics. They also attended the Navy dinner which serves as a forum for Navy Medicine Research and Development Leaders to discuss research and development efforts and provide strategic guidance to Active Duty and Navy Civilian researchers.

Ms. Roxana Lescano of the U.S. Naval Medical Research Unit SOUTH was awarded the MHSRS 2024 Distinguished Service Award for her “unwavering dedication to advancing research integrity and compliance with the Military Health System.” DON HRPP congratulates Ms. Lescano for the well-deserved award. Ms. Lescano’s impressive accomplishments are highlighted at: <https://health.mil/News/Gallery/Dvids-Videos/2024/09/05/video935798>

### Command Naming Convention for Research Protocols & IRB Meeting Minutes

It’s the start of a new fiscal year! Remember to begin using the “2025.0001” naming convention for new approved research protocols and IRB meeting minutes initiated on or after 1 October 2024. It is not necessary to rename existing protocols. The FY25 naming convention document is available on the DON HRPP milSuite page at: <https://www.milsuite.mil/book/groups/don-hrpp>

### Recap of DOHRP Seminars

The Department of Defense Office for Human Research Protections (DOHRP) held two informative seminars in September featuring individuals with various backgrounds who presented on a variety of topics.

On 17 September 2024, DOHRP hosted the Seminar on Human Subjects Research Ethics for Responsible Innovation using Federal Funds (SHERIFF), which offered the opportunity to hear from interagency partners who discussed their agency’s regulatory programs and ethical oversight of research. Representatives from several federal agencies presented including individuals from the National Institute of Standards and Technology, Department of Energy, and Department of Veterans Affairs, as well as others.

On 26 September 2024, the DoD HRPP Day provided attendees with significant information related to human research protections presented by experts from the Naval War College, Defense Human Resources Activity, the Air Force Research Laboratory, U.S. Army Medical Research and Development Command, Defense Health Agency, and other institutions.

DON HRPP appreciates all those from the DON research community who participated in these events, as the seminars offered valuable learning opportunities for all who attended as well as venues for networking.

### CLaSS Will Soon Be In Session

Please join us for the first day of CLaSS (Command Learn and Share Series) on 14 November 2024 at 1300 EST. The series is designed to provide an interactive forum for inter-command knowledge exchange and discussions of various HRPP topics.

The inaugural virtual session will be led by DON HRPP and will consist of reviewing a published study entitled, “Suicide risk communication and intervention preferences for veterans and service members” conducted by Stop Soldier Suicide, followed by a discussion of the unique HRPP requirements to consider when reviewing research studies involving this population. We hope this session sparks collegial dialogue as we explore how different commands would review and approve this study, as well as the safety parameters that commands would implement.

Event invitations with the session link, published study, and supplemental materials will be distributed soon, so keep a close eye on your inboxes!

We look forward to seeing you on the first day of CLaSS!